IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, Plaintiff, v. WHOLESOME SOY PRODUCTS, INC., a corporation, and JULIA TRINH, an individual, and PAUL TRINH, an individual, Defendants.	)	CIVIL ACTION NO. _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, respectfully represents to this Court as follows:

INTRODUCTION

1. The United States of America brings this action under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Wholesome Soy Products, Inc. ("Wholesome Soy Products" or "the firm"), Julia Trinh, and Paul Trinh (collectively, "Defendants"), from violating 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment of one or more components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this matter under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Wholesome Soy Products is an Illinois corporation that received, processed, manufactured, prepared, packed, held, and distributed ready-to-eat ("RTE") mung bean and soybean sprouts ("sprouts") until early November 2014. Wholesome Soy Products' principal place of business is located at 1150 West 40th Street, Chicago, Illinois (the "facility"), within the jurisdiction of this Court.

5. Defendant Julia Trinh ("J. Trinh") is the owner and President of Wholesome Soy Products. Until recently, she was responsible for purchasing supplies and equipment, managing contracts and agreements with contractors, handling customer service, hiring, firing, scheduling training, implementing procedures, and maintaining quality assurance. She performed her duties at the facility, within jurisdiction of this Court.

6. Defendant Paul Trinh ("P. Trinh") was a manager at Wholesome Soy Products. Until recently, he was responsible for production operations, sprout processing, and training new hires. He performed his duties at the facility, within jurisdiction of this Court.

LISTERIA MONOCYTOGENES

7. *L. mono* is a bacterium that can contaminate foods and can cause a mild illness, called listerial gastroenteritis, or a severe, sometimes life-threatening illness, called invasive listeriosis. Persons who have the greatest risk of experiencing listeriosis after consuming foods contaminated with *L. mono* are fetuses and neonates who are infected after the mother is exposed to *L. mono* during pregnancy, the elderly, and persons with weakened immune systems. Invasive listeriosis is characterized by a high case fatality rate.

8. Unlike many other foodborne pathogens, *L. mono* is capable of adapting and growing at refrigerated temperatures. *L. mono* is also capable of surviving and growing under

other adverse conditions, such as high salt or high acid (low pH) environments. *L. mono* thrives in moist environments, such as sprout growing environments, where, unless proper precautions are taken, it may colonize equipment and the environment. Consequently, *L. mono* is a significant public health risk in RTE foods, such as Defendants' sprouts, and is difficult to eliminate once it becomes established in a food manufacturing environment.

9. Recent advances in genetic testing using whole genome sequencing of *L. mono*, together with traditional epidemiological investigations, have allowed public health officials to connect sporadic cases of listeriosis to specific foods manufactured by specific manufacturers.

LISTERIOSIS OUTBREAK

10. On November 7, 2014, the Centers for Disease Control and Prevention ("CDC") reported that it was collaborating with the U.S. Food and Drug Administration ("FDA") and two states to investigate a multi-state outbreak of human infections linked to *L. mono*. The outbreak consisted of five people in two states (Illinois and Michigan) with onset dates of listeriosis ranging from June through August 2014. All five people were hospitalized, and two deaths were reported. Two of the five people were interviewed, and both reported consuming bean sprouts in the month before becoming ill. Using whole genome sequencing analysis, the strains of *L. mono* isolated from sprouts and environmental swabs collected by FDA during inspections at Defendants' facility were found to be highly related to the *L. mono* strains isolated from the clinical samples of the five people. CDC reported that the high degree of genetic similarity between isolates from the ill people and isolates from the sprouts and environmental samples collected at Defendants' firm showed that Defendants' sprouts were contaminated with a strain of *L. mono* that can cause serious illness. Although there was limited information regarding the

source of the sprouts that the ill people consumed, CDC and FDA concluded that these illnesses could be related to sprouts from Wholesome Soy Products.

11. On November 13, 2014, CDC announced that the Illinois Department of Public Health was working to embargo all products from Wholesome Soy Products and other retailers that had their products at that time.

DEFENDANTS' VIOLATIONS

12. Defendants violated 21 U.S.C. § 331(k) by causing food held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

13. Defendants' RTE sprouts are food within the meaning of 21 U.S.C. § 321(f).

14. The seeds Defendants used to grow sprouts were shipped to them in interstate commerce. For example, Defendants purchased and received mung bean seeds from a distributor in Louisville, Kentucky, that originated from China.

15. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it was prepared, packed, and/or held under insanitary conditions whereby it may have become contaminated with filth or have been rendered injurious to health. The insanitary conditions included the prolonged presence of *L. mono* in Defendants' facility and insanitary employee practices.

16. Because sprouts are high in nutrients and are produced under warm and wet conditions, the sprouting process is ideal for the growth of multiple microbial-pathogens that may be present. Sprouts have been associated with numerous outbreaks of foodborne illness. Because sprouts may be consumed in their raw state without further processing to eliminate pathogens, the manner in which they are produced, packed, and

held is crucial to ensuring that the potential for microbial contamination is minimized, thereby reducing the risk of illness to consumers.

FDA INSPECTIONS

17. Inspections of Defendants' facility by FDA have established that Defendants have a history of operating under insanitary conditions and violating the Act.

The October and September 2014 Inspections

18. FDA's most recent inspection of Defendants' facility was conducted from October 7 to October 31, 2014 ("the October Inspection") and was a follow-up to FDA's prior inspection conducted from August 12, 2014 to September 3, 2014 (the "September Inspection"). During the October Inspection, FDA investigators observed insanitary conditions and significant sanitary deficiencies that were repeat observations from the September Inspection of Defendants' facility. These repeated deficiencies included, but were not limited to, the following:

(a) Employee practices that allowed for potential contamination of food contact surfaces and food products. For example, employees who handled food or food contact equipment exited and re-entered the sprout production area while wearing boots and aprons, and they resumed handling food and food contact equipment without changing, cleaning, or sanitizing their boots and aprons;

(b) Cleaning practices that were inadequate;

(c) Pest control measures that were ineffective;

(d) Equipment and utensils that were not properly maintained;

(e) A sprout production environment that was not properly maintained; and

(f) A plant that was not constructed in such a manner as to allow floors and walls to be adequately cleaned and kept in good repair.

FDA LABORATORY TESTING

19. Using samples from the September Inspection, an FDA laboratory found that two samples from mung bean sprouts, which were distributed to customers, and one sample of spent mung bean sprout irrigation water, tested positive for *L. mono*. FDA's laboratory also found that an additional twenty-five environmental subsamples that were collected from the September Inspection tested positive for *L. mono*. FDA concluded that a resident strain of *L. mono* had colonized the facility and was getting into Defendants' sprouts.

20. FDA took additional samples from the facility during the October Inspection, and FDA again found *L .mono* isolates in some samples. Specifically, an FDA laboratory found that three environmental subsamples from Wholesome Soy Products' sprout production area tested positive for *L. mono*, and six environmental subsamples from the firm's warehouse and cooler floors tested positive for *L. mono*. These strains were highly related to the strains of *L. mono* that were found during the September Inspection.

NOTICE OF VIOLATIONS AND DEFENDANTS' RESPONSE

21. FDA has repeatedly warned Defendants about serious, violative conditions and conduct at the facility. FDA issued a Form FDA-483, List of Inspectional Observations ("Form FDA-483") at the conclusion of both the September and the October Inspections, and during each inspection the investigators verbally discussed their concerns with Defendant J. Trinh.

22. Defendant J. Trinh responded to the Form FDA-483 that was issued during the September Inspection in a letter. In her response, Defendant J. Trinh informed FDA that the firm had ceased all bean sprout production on August 27, 2014, after she was notified by FDA that Defendants' mung bean sprouts tested positive for *L. mono*. Defendant J. Trinh stated that the

firm had retained a food safety-consulting firm and an industrial cleaning and sanitizing chemical supplier.

23. However, Defendant J. Trinh's letter also revealed that Defendants resumed their sprout production on September 15, 2014. Defendants resumed production even though they: (1) did not take adequate steps to prevent the presence and risk of *L. mono* contamination; (2) did not demonstrate that they had adequately addressed each violation observed by FDA; and (3) did not verify that their employees had been adequately trained on sustainable sanitation practices and procedures.

24. On September 30, 2014, FDA notified Defendant J. Trinh that twenty-five of the environmental subsamples taken during the September Inspection tested positive for *L. mono*.

25. During the October Inspection, FDA notified Defendant J. Trinh that nine subsamples from the October Inspection tested positive for *L. mono*. FDA informed Defendant J. Trinh that whole genome sequencing demonstrated a close association between the clinical *L. mono* isolates from the people who became ill in the listeriosis outbreak and the *L. mono* that was isolated from samples that were taken at the facility.

26. On November 7, 2014, FDA held a regulatory meeting with Defendant J. Trinh to discuss the September and the October Inspections. FDA and Defendant J. Trinh discussed the changes that the firm had implemented since the October Inspection. FDA described why these changes were insufficient. Defendant J. Trinh committed that Wholesome Soy Products would cease production and distribution of sprouts, effectively shutting down the firm. Ms. Trinh also stated that Defendants would consider a proposed consent decree with FDA.

27. While Defendants have made some corrections, they have failed to institute practices and procedures necessary to ensure that the facility can receive, process, manufacture, prepare, pack, hold, and distribute food under sanitary conditions and that *L. mono* is eradicated from the facility. The facility is not currently producing or distributing food, but nothing prohibits Defendants from resuming production without adequate corrective actions. Based on the foregoing, Plaintiff is informed and believes that, unless restrained by order of the Court, Defendants will violate 21 U.S.C. § 331(k) again.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates), who receive notice of the Court's order from, directly or indirectly, violating 21 U.S.C. § 331(k), by doing and causing to be done any act that causes any article of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such article is held for sale after shipment of one or more of its components in interstate commerce;

II. Order Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates), who receive notice of the Court's order to cease, directly or indirectly, receiving, processing, manufacturing, preparing, packaging, holding, and

distributing any article of food within the meaning of 21 U.S.C. § 321(f), at or from Defendants' facility (and any other or new location at or from which Defendants receive, process, manufacture, prepare, pack, hold, or distribute food), unless and until Defendants bring their operations into compliance with the Act and its implementing regulations to the satisfaction of FDA; and

III. Award the United States its costs herein, including the costs of investigation to date, and such other relief as the Court may deem just and proper.

Dated this 3rd day of April, 2015

BENJAMIN C. MIZER
Acting Assistant Attorney General
Civil Division

JONATHAN F. OLIN
Deputy Assistant Attorney General
Civil Division

MICHAEL S. BLUME
Director
Consumer Protection Branch

/s/ Daniel M. Baeza
DANIEL M. BAEZA
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch
450 Fifth St., NW, 6400-S
Washington, DC 20001

OF COUNSEL

WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

PERHAM GORJI
Deputy Chief Counsel, Litigation

CHARLOTTE HINKLE
Assistant Chief Counsel for Enforcement
U.S. Department of
Health and Human Services
Office of the General Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993